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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,510	11/08/2001	Charles S. Schasteen	NVI 5183.1	9657

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SENNIGER POWERS LEAVITT AND ROEDEL
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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,510	SCHASTEEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30,113-119 and 136-148* is/are pending in the application.

4a) Of the above claim(s) *144 and 145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30,113-119,136-143 and 146-148* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment and response filed February 18, 2004 is acknowledged. Claims 6, 19, 113,116, 118, 136 and 139-141 have been amended. Claims 144-148 have been added. Claims 31-112 and 120-135 have been cancelled.

2. ***Election/Restriction***

Newly submitted claims 144 and 145 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Newly submitted claims 144-145 are drawn to a composition comprising viable, sporulated oocysts of at least one species of coccidial protozoa and an anti-forming agent where as claims 1-15, 19-23, 113-119 and 136-143 are drawn to a composition for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate further comprising *Propionibacterium acnes*. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 144-145 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. In view of Applicant's amendment, response and the following objections and rejections are withdrawn:

a) objection to the specification, page 2, paragraph 2.

b) objection to the specification, page 2, paragraph 3.

c) objection to the drawings, page 2, paragraph 4 (new formal drawing submitted February 18, 2004).

d) rejection of claims 6, 116, 118, 136 and 141 under 35 U.S.C. 112, second paragraph, page 3, paragraph 5.

e) rejection of claims 113-119 and 136-143 under 35 U.S.C. 112, second paragraph, page 3, paragraph 6.

f) rejection of claims 136-143 under 35 U.S.C. 112, second paragraph, page 3, paragraph 7.

g) rejection of claims 1-22, 113-119,136-137, 140-142 and 146-148 under 35 U.S.C. 102(b), pages 4-7, paragraph 8.

h) rejection of claims 1-30, 113-119, 136-137, 140-143 and 146-148 under 35 U.S.C. 103(a), pages 7-9, paragraph 9.

New Grounds of Rejection

Specification

5. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 41. Applicant is required to review the specification for hyperlinks and delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

6. The use of the trademark has been noted in this application, for example on page 30. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 136-143 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 136 recites the term "rate sufficient". It is unclear as to what the Applicant is referring? Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1-25, 29-30, 113-119, 136-142 and 146-148 are rejected under 35 U.S.C. 102(a) as anticipated by Conkle et al *(WO 00/50072, published August 31, 2000).*

Claims 1-25, 29-30, 113-119, 36-142 and 146-148 are drawn to a composition for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is

sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate.

Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8). Claim limitations such as "the composition ameliorates a decline or decrease in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as inherent and as a limitation of intended use. The package insert (instructions) does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. If there is no novelty in a composition itself, then a patent cannot be properly granted on the composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new. Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a

mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use. It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a). Thus the instructions for use included in composition constitute an "intended use" for that composition. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963). In the instant case, the claims are drawn to a composition which comprises oocysts and instructions for administration of the said composition to an animal. The intended use which is recited on the package insert lacks a function relationship to the composition because the insert does not physically or chemically affect the chemical nature of the composition and

furthermore, the composition can still be used by the skilled artisan for other purposes. Therefore, instructions for administering the composition is unpatentable over the prior art because the composition functions equally effectively with or without the package insert, and accordingly *no functional relationship exists between the instructions for use and the composition*. Thus, the instructions on the package insert bears no patentable weight with regard to double patenting, 102, and 103 rejections. The claim limitation "wherein said oocysts have been separated by tangential flow filtration ~~form~~ from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in

the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon. Conkle et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-30, 113-119, 136-143 and 146-148 are rejected under 35 U.S.C. 103(a) as unpatentable over Conkle et al *(WO 00/50072, published August 31, 2000)* in view of Brown et al *(U.S. Patent No. 6, 019, 985, published February 1, 2000)*.

Claims 1-30, 113-119, 136-143 and 146-148 are drawn to a composition for the prevention or control of coccidiosis comprising viable wild type sporulated oocysts of at least one species of protozoa known to cause coccidiosis wherein said composition is

sterile and contains at least about 10,000 oocysts per milliliter and less than about 0.8% by weight of alkali metal dichromate.

Conkle et al teach compositions comprising coccidial oocysts from *Eimeria maxima*, *E. acevulina* and *E. tenella* (page 3). Conkle et al teach that the oocyst concentration is about 10^4 to about 10^6 oocysts/ ml (page 3). Conkle et al teach that in a preferred embodiment of the invention the oxidant is hydrogen peroxide (page 8).

Conkle et al do not teach the use of *Propionibacterium acnes*.

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases (column 3, lines 20-26 and column 4, lines 15-21). Brown et al teach that the amount of *Propionibacterium acnes* in the composition is about 0.5 mg to about 10 mg dried weight per milliliter of diluent (column 4, lines 15-21). Brown et al teach that other materials such as antibiotic, for example gentamicin may be added to the composition comprising *Propionibacterium acnes* (column 4, lines 7-14). Claim limitations such as, "a kit", "the composition ameliorates a decline in post-challenge performance" and "a ratio is defined by the minimum immunizing dose and amount determined by storage high-life determinations" are being viewed as limitations of intended use. The claims limitation "wherein said composition contains at least about 30 milligrams (dry weight of *P. acnes* per milliliter is being viewed as a limitation of optimizing experimental parameters since Brown et al teach that other initial concentrations of P acnes suspension are within the scope of the invention because the actual administration to the chick is

adjusted and diluted for optimum dosages (column 4, lines 19-22). The claim limitation "wherein said oocysts have been separated by tangential flow filtration from an aqueous sporulation medium is a process limitation. It should be remembered that the products of the prior art reference appear to be the same or an obvious or analogous variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 29222-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

It would be *prima facie* obvious at the time the invention was made to add the composition comprising *Propionibacterium acnes* as taught by Brown et al to the compositions comprising oocysts from the genus *Eimeria* of Conkle et al because

Brown et al teach compositions comprising *Propionibacterium acnes* and normal saline used for stimulating non-specific cell mediated immune responses in poultry at an age as early as one or even *in ovo* and to combat coccidiosis and other poultry diseases. It would be expected barring evidence to the contrary that a composition comprising sporulated oocysts, a diluent, a buffer and a bactericide would be effective in preventing coccidiosis in animals.

Conclusion

10. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 12, 2004

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